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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/022,799	12/20/2001	Beuford Arlie Bogue	24720	4794

7590 08/04/2004

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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 08/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/022,799

Applicant(s)

BOGUE, BEUFORD ARLIE

Examiner

Lakshmi S Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 28 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5-28-04 has been entered.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 13 and 24 are rejected under 35 U.S.C. 101 because

the claimed invention is directed to non-statutory subject matter. Instant claims recite that the excipient could be natural product and reads on any product that occurs in nature. A product of nature is a non-statutory subject matter and cannot be patented.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-14 and 18-25 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 99/40943 (WO).

WO discloses solubilizing delivery systems for poorly soluble drugs and the process of solubilizing the drugs so as to enhance the solubility of the drugs. The process of WO comprises processing of particles of at least one active agent and at least one solubilizing agent (surfactant) at temperatures below the melting points of both drug and surfactant (eutectic temperature). The processing further involves applying shear forces after melting the drug and surfactant at the eutectic temperatures (page 2, lines 20-31; page 3, lines 6-16 and lines 26-30 & page 4, lines 1-3), resulting in crystalline drug particles coated with the surfactant. WO discloses the claimed drugs and surfactants suitable for the invention on page 5 and 6; and their amounts on page 4, lines 17-25, all of which are claimed in the instant application. WO discloses employing micronized drug (example I) for the processing and hence meet claim 21. With respect to the particle size, WO states that the particle size before processing is less than 10 microns or even preferably less than 6 microns (page 5, lines 16-18) and the process of applying high shear, disclosed by WO, inherently yields crystalline particles of much smaller size. The claimed matrix, miscibility and the absence of bonding between the drug and the surfactant is inherent to the composition of WO because the drug and surfactant are processed in exactly the same way as described in the instant specification. Accordingly, WO anticipates instant claims.

***Claim Rejections - 35 USC § 103***

Claims 15-17 and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/40943 (WO).

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WO, discussed above, fails to specifically teach the carrier, diluent, binder etc., for the drug. However, WO suggests mixing the surfactant coated drug particles (after processing) with various pharmaceutical ingredients such as binders, flow control agents, fillers, sweeteners etc. Accordingly, it would have been within the scope of a skilled artisan at the time of the instant invention to include any suitable pharmaceutical additive such as a binder or sweetener depending the desired pharmaceutical effect.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13 and 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Instant claims define organic excipients to include low molecular weight oligomers, natural products and organic solvents along with the other claimed surfactants. A careful review of the instant specification does not show that applicants are in possession of all the possible oligomers, natural products and organic solvents because the instant specification does not describe the various possible oligomers or natural products or organic solvents that are suitable as surfactants. Instant specification merely recites oligomers, natural products and organic solvents but fails to state as what they constitute. This is a written description rejection.

Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites limitations “a surfactant-drug matrix at a temperature above said matrix’s melting temperature” and “said drug composition further comprises micro or nano-sized crystals of said drug substance coated said surfactant at room temperature, said crystals formed while being said matrix is cooled to room temperature under shearing force”, which are indefinite because it is unclear from the above limitations if applicants’ are claiming a matrix formed by melting at a temperature above the melting temperature of the matrix (a product by process) or a matrix already formed and has a temperature above the melting temperature. If the former is being claimed, then the claim does not clearly state so. With respect to the second limitation, it is examiner’s understanding that the drug crystals are coated with the surfactant. However, the expression “drug substance coated said surfactant” is not the same as what is being claimed. A clarification and correction is requested.

### ***Response to Arguments***

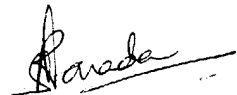
Applicant's arguments with respect to claims 1-28 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.30 AM -4.00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala  
Examiner  
Art Unit 1615  
August 3, 2004